

UNITED STATES DISTRICT COURT  
DISTRICT OF MINNESOTA  
Criminal No. 05-282 (MJD/JJG)

UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	<b>UNITED STATES' OPPOSITION</b>
	)	<b>TO DEFENDANT SMITH'S MOTION</b>
v.	)	<b>FOR A NEW TRIAL</b>
	)	
(1) CHRISTOPHER WILLIAM SMITH,	)	
	)	
Defendant.	)	

The United States of America, by and through its attorneys, Rachel K. Paulose, United States Attorney for the District of Minnesota, and Nicole A. Engisch and Elizabeth C. Peterson, Assistant United States Attorneys, opposes Defendant Smith's motion for a new trial pursuant to Fed R. Crim. P. 33.

Under Rule 33, the Court may grant a new trial only if the "interest of justice so requires." The district court's authority to grant a new trial should be exercised "sparingly and with caution." United States v. Ramirez, 362 F.3d 521, 525 (8th Cir. 2004 (citations omitted)). The defendant's motion for a new trial should be denied because there is no merit to any of his four grounds of alleged error.

Defendant's first two grounds of alleged error are that the Court erred by allowing only an "unqualified 'expert'" to testify to the prevailing standards of medical practice in the United States and by instructing the jury to consider prevailing standards of medical practice in the United States when there was no

qualified testimony concerning such practice. Both grounds are without merit because the government introduced qualified testimony both from Dr. Philip Mach and from Carmen Catizone concerning the prevailing standards of medical practice in the United States.

Dr. Mach testified about how he typically practices medicine (e.g., that he typically sees the patient in person, takes a medical history, and evaluates the patient's need for medication) and about how his Internet prescribing for Defendant Smith was, in contrast, outside the usual course of professional practice and not for a legitimate medical purpose.<sup>1</sup> There was no error in allowing this testimony. To the extent Dr. Mach gave his opinion that his own Internet prescribing behavior was inconsistent with prevailing standards of medical practice, that testimony was "(a) rationally based on the perception of the witness" and "(b) helpful to a clear understanding of the witness' testimony or the determination of a fact in issue." Fed. R. Evid. 701. "Personal knowledge or perceptions based on experience is a sufficient foundation for such testimony." United States v. Oslund, 453 F.3d 1048, 1058-59 (8th Cir. 2006) (quoting In re Air Crash At Little Rock Ark., 291 F.3d

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<sup>1</sup>To the government's recollection, at the time Dr. Mach's testimony was introduced, there were no objections by the defendant. Therefore, the matter must be reviewed under the plain error standard. See United States v. McBride, 862 F.2d 1316, 1319 (8th Cir. 1988) (holding that defendant's failure to object at trial generally precluded him from asserting the error in a motion for new trial absent plain error).

503, 515 (8th Cir. 2002)). Because Dr. Mach was the issuing physician, his testimony that his Internet proscriptions were outside the usual course of professional practice and not for a legitimate medical purpose was sufficient evidence on this issue. See United States v. Hayes, 595 F.2d 258, 261 (5th Cir. 1979) (in case against pharmacist, court rejected sufficiency argument where "[t]he doctor himself testified that during the period in question he had no legitimate patients and that any prescriptions written by him were not written in the usual course of medical practice or for a legitimate medical purpose.").

But the government also offered qualified expert testimony from Carmen Catizone, M.S., R.Ph., D.Ph., on the issue of prevailing standards of medical practice.<sup>2</sup> The basis for his testimony was that Dr. Catizone, in addition to being the chief executive officer and executive director for the National Association of the Boards of Pharmacy, is a pharmacist, and pharmacists are required by law (21 C.F.R. 1306.04, among others) to determine for themselves if prescriptions are issued in the usual course of professional practice and for a legitimate medical purpose.<sup>3</sup> Dr. Catizone testified that he had reviewed Government

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<sup>2</sup>The defendant did raise an objection to this testimony at trial. The objection was overruled based on the arguments of the government which were consistent with the arguments made here.

<sup>3</sup>It should be noted that there is no requirement that such expert testimony come from a licenced physician. United States v. Jones, 570 F.2d 765, 769 (8th Cir. 1978) (court upheld conviction

Ex. 169, the information that Dr. Mach relied upon in issuing prescriptions, and based on his experience and expertise, he concluded that there was not enough information for a physician to determine whether or not a person actually needed the prescription order. Transcript of Testimony of Carmen Catizone at 31. Specifically, he testified that "[b]ased upon state and federal law that defines a valid prescription and the conditions that are necessary to deem they're valid, this information doesn't meet that requirement. It also doesn't meet the requirement of the standards of care for a prescription to be dispensed or a prescription to be prescribed." Id. at 34.

The defendant's next ground of alleged error is that the Court erred by refusing to instruct the jury that a good faith reading of 21 C.F.R. § 1306.04 could support an acquittal. There is no merit to this argument. "A district court has broad discretion when formulating jury instructions, and a defendant is entitled to a requested instruction only if 'it correctly states the law and is supported by the evidence.'" United States v. Poe, 442 F.3d 1101, 1103 (8th Cir. 2006) (quoting United States v. Johnson, 278 F.3d 749, 751-52 (8th Cir. 2002)).

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after rejecting defense argument that there was no qualified expert testimony on the issue of outside the usual course of professional practice where government's expert witness was not an M.D., but possessed a Ph.D. in pharmacology and taught at the Washington University Medical School).

It would in any event have been error for the Court to have instructed the jury in this drug conspiracy case that a defendant who incorrectly reads the law may be acquitted. There was no factual basis to support such a proposed instruction, as there was no evidence in the case whatsoever that the defendants acted in reliance on a misreading of 21 C.F.R. § 1306.04. None of the defendants testified, and no such evidence was otherwise introduced.

Secondly, the proposed instruction was an incorrect statement of the law applicable in this case. Essentially, the proposed instruction was based on the Supreme Court's decision in Cheek v. United States, 498 U.S. 192 (1991). In Cheek, the defendant was charged with tax evasion and failure to file tax returns. In that context, the Court held that a good faith misunderstanding of the law or a good faith belief that one is not violating the law could negate willfulness. As the Court noted on the record following the charge conference, the Eighth Circuit has declined to extend the Cheek decision beyond the tax context in which it was decided. See, e.g., United States v. Hildebrandt, 961 F.2d 116, 188 (8th Cir. 1992) (refusing to extend Cheek's holding to a false statement case because such a charge did not involve a willful failure to act, but the willful doing of a prohibited act); United States v. Dureinksy, 945 F.2d 1006, 1012 (8th Cir. 1991) (noting that district courts have wide discretion to determine appropriate jury

instructions and holding that Cheek does not apply to a case in which the defendant was charged under a general conspiracy statute in which willfulness was not an express element, as opposed to a criminal tax statute).<sup>4</sup>

The defendant's final ground of alleged error is that the Court erred by refusing to instruct the jury that the seminal question of fact was whether the prescriptions in issue were issued in the usual course of Dr. Mach's practice rather than in the usual course of the prevailing standards of medical practice in the United States. This argument, too, is without merit. While the defendants were permitted throughout the trial to argue, via cross examination and otherwise, that the "usual course of professional practice" is determined by a subjective standard, that has never been the law. The Courts that have examined the question of whether the "usual course of professional practice" is based on a subjective or objective standard have uniformly held that it is an objective standard. See United States v. Hurwitz, 459 F.3d 463, 478 (4th Cir. 2006) ("We believe that the inquiry must be an objective one, a conclusion that has been reached by every court to

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<sup>4</sup>In addition, the jury was properly provided with a good faith instruction, based on a standard instruction from O'Malley, Grenig, and Lee, Federal Jury Practice and Instructions, § 64.16, that informed the jury they could acquit the defendant if they agreed the defendant acted in the good faith belief that the prescriptions issued were valid. The jury was also instructed that a defendant's good faith reliance on the advice of counsel (here there were at least four attorneys involved in rendering advice) could support an acquittal.

specifically address the question." ). These uniform holdings are based on the Supreme Court's 1975 decision in United States v. Moore, 423 U.S. 122 (1975).

For example, in United States v. Vamos, 797 F.2d 1146 (2<sup>nd</sup> Cir. 1986), cert. denied, 479 U.S. 1036 (1987), the court stated:

The term "professional practice" refers to generally accepted medical practice; a practitioner is not free deliberately to disregard prevailing standards of treatment. United States v. Norris, 780 F.2d 1207, 1209 (5<sup>th</sup> Cir. 1986). In short, the doctor must act in the good faith belief that his distribution of the controlled substance is for a legitimate medical purpose and in accordance with the usual course of generally accepted medical practice. In United States v. Moore, 423 U.S. 122, 138-39, 96 S. Ct. 335, 343-44, 46 L.Ed.2d 333 (1975), the Court quoted and implicitly approved a jury instruction explaining that a physician could be convicted if the jury found that he knowingly distributed controlled drugs "other than in good faith for detoxification in the usual course of a professional practice and in accordance with a standard of medical practice generally recognized and accepted in the United States." Id. at 138-39, 96 S. Ct. at 343-44.

797 F.2d at 1151 (emphasis added). The court further explained:

To permit a practitioner to substitute his or her views of what is good medical practice for standards generally recognized and accepted in the United States would be to weaken the enforcement of our drug laws in a critical area. As the Supreme Court noted in Moore, "Congress intended the CSA to strengthen rather than to weaken the prior drug laws." 423 U.S. at 139, 96 S. Ct. at 343. Faced with a situation similar to that presented here, the Fifth Circuit approved an objective standard for determining what constitutes accepted medical practice, stating, "[o]ne person's treatment methods do not alone constitute a medical practice." United States v. Norris, supra, 780 F.2d at 1209. The Sixth Circuit has likewise followed an objective "reasonableness" standard, approving an instruction to the effect that a physician's good faith dispensation of a controlled substance in the usual course of his professional practice "connotes an

observance of conduct in accordance with what the physician should reasonably believe to be proper medical practice." United States v. Voorhies, 663 F.2d 30, 33-34 (6<sup>th</sup> Cir. 1981).

797 F.2d at 1153 (emphasis added); see also United States v. Singh, 390 F.3d 168, 185 (2d Cir. 2004); United States v. Leal, 75 F.3d 219, 226 (6th Cir. 1996).

Additionally, in United States v. Norris, 780 F.2d 1207, 1209 n. 2 (5<sup>th</sup> Cir. 1986), the court approved the following instruction, which is very close to the language of the instructions in this case:

A controlled substance is prescribed by a physician in the usual course of a professional practice and, therefore, lawfully, if the substance is prescribed by him in good faith, medically treating a patient in accordance with a standard of medical practice generally recognized and accepted in the United States.

The cases in this area from the Eighth Circuit, in which courts assume an objective standard without any challenge to that standard by defense, are in accord. See, e.g., United States v. Katz, 445 F.3d 1023, 1029 (8th Cir. 2006); United States v. Jones, 570 F.2d 765, 769 (8th Cir. 1978); United States v. Plesons, 560 F.2d 890, 896 (8th Cir. 1977); United States v. Kershman, 555 F.2d 198, 201 (8th Cir. 1977).

Thus, in this case, the jury was properly instructed that the phrase "[u]sual course of professional practice' means that the practitioner acted in accordance with a standard of medical practice generally recognized and accepted in the United States."

The jury was also properly instructed that, "[i]n issuing prescriptions, practitioners are not free to disregard prevailing standards of treatment."

**CONCLUSION**

For all of these reasons, and upon the record and evidence in this case, the government respectfully requests that the Court deny Defendant Smith's motion for a new trial pursuant to Fed. R. Crim P. 33.

Dated: December 4, 2006

Respectfully submitted,

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